

Remarks/Arguments:

This amendment does not cancel any claims, and is provided to add new dependent claims 7-17 and amend independent claims 1, 2 and 3. However, in doing so, no new matter has been added. Upon entry of this amendment, claims 1-17 will be pending, wherein claims 1-3 are independent.

Rejections of the Claims under 35 U.S.C. 103

The Examiner has maintained the rejection of claims 1 and 6 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent Publication No. 2002/0055711 of Lavi et al. (hereinafter Lavi) in view of U.S. Patent No. 5,976,111 of Hart (hereinafter Hart).

The Examiner points to Lavi as disclosing a safety member, biasing spring element, and rotatable door disposed on the bottom surface of the housing as recited. Specifically, the Examiner points to the shield 231, spring 232, and latches 237 of Lavi Figs. 18-20 as constituting such a safety member, biasing spring element, and rotatable door, respectively.

As noted in the earlier response, Lavi describes a spring-urged guard that extends from a bottom of a device. The latches 237 of Lavi are configured to secure the guard 231 against a top surface of the bottom of the device to keep the guard within the device, and to be pushed free of the bottom of the device by downward travel of element 270, to thereby allow the guard 231 to extend from a bottom surface of the device as urged by spring 232. However, in doing so, the latches 237 which allegedly constitute the *rotatable door*, are entirely contained *within the device*. In contrast, the Applicants describe a system and method wherein the rotatable door is disposed on the bottom surface (and the bottom surface is configured to contact the skin surface). As such, the rotatable door as recited is disposed differently than the deflectable latches 237 of Lavi.

In the Advisory Action of February 28, 2011, the Examiner asserts that “the claim does not recite that the rotatable door is configured to contact the skin” and finds “the indicated door (latches) of Lavi to be disposed on the bottom surface of the housing which contacts the skin”.

The Applicants disagree and note that the claim recites a bottom *surface* of the housing is configured to contact the skin surface, and a rotatable door is *disposed* on the bottom *surface* of the housing. No door nor latches 237 are disposed on the bottom *surface* of Lavi, rotatable or otherwise, and the deflectable latches 237 are positioned *within* the device, and are simply part of the needle shield 231 which has a bottom surface, or viewed in another manner, contact a top surface of the bottom of the device. However, nothing is disposed upon the bottom surface of the needle shield 231.

However, to expedite prosecution, the Applicants have amended independent claim 1 to recite that the rotatable door is *adapted to contact a skin surface of a patient* and is disposed upon the bottom surface of the housing.

The Examiner has also maintained the rejection of claims 2-5 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lavi in view of Hart.

The Applicants recite a safety member *held in place by the device activation button*, and *released by activation of the device activation button*. However, the shield 231 of Lavi is held in place by the latches 237 sitting on the top surface of the bottom of the device (see Fig. 17 and paragraph 127). That is, the shield 231 of Lavi is held from activation by interference with the top surface of the bottom of the device, and not by an activation button, such as the actuator 260. The downward movement of the second actuator 260 to place the needle pushes the latches 237 and more specifically, pushes the latches 237 from the top surface of the bottom of the device, but no embodiment shows the shield 231 held in place by the actuator 260 or any other device activation button.

In the Advisory Action of February 28, 2011, the Examiner asserts that “the claims do not recite any limitations as to what constitutes device activation”. However, even in this case, the Applicants assert that the shield 231 of Lavi is held from activation by interference with the top surface of the bottom of the device, and not by any button, and at most is simply released by the downward movement of the second actuator 260.

However, to expedite prosecution, the Applicants have amended independent claims 2 and 3 to recite that the device activation comprises at least activation button movement and

in doing so, *contact* between a *safety member surface* and the *activation button* is released, such that the safety member is no longer prevented from linear or rotational movement by such contact with the activation button. Specifically, the Applicants have amended the claims to recite a safety member comprising at least one surface configured to contact and be held in place by the device activation button to prevent linear or rotational movement, and wherein the safety member is released by movement of the device activation button from contact with the safety member.

As noted above, the shield 231 of Lavi is held from activation by interference with the top surface of the bottom of the device, and not by contact between the safety member and an activation button. The downward movement of the second actuator 260 pushes the latches 237 from the top surface of the bottom of the device, but no embodiment shows the shield 231 held in place by a securing contact with the second actuator 260.

The Examiner has also maintained the rejection of claims 3 and 4 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,500,150 of Gross et al. (hereinafter Gross 1) in view of U.S. Patent No. 5,997,501 of Gross et al. (hereinafter Gross 2).

In the Applicants' disclosure, securing of a safety member can be achieved through the use of, for example, the door 790 and door latch 791 of Fig. 39 (see also paragraph 319), or the lock arm 1034 of Fig. 123 (see also paragraph 342). In this case, the device can be positioned against a skin surface, and movement of the device activation button releases the latch or lock arm. However, as the device is adhesively positioned against a user's skin, no movement of the safety member is allowed, but the safety member is free to move upon removal of the device. In doing so, the Applicants recite a system and method wherein the safety member is secured through *contact with* the activation button while in the first position such that the safety member is substantially co-planar with the bottom surface of the housing, such as in a pre-use position, and is released by movement of the device activation button from contact with the safety member. If the device is not properly activated in this

manner, the safety member cannot be inadvertently deployed, even if adhesion somehow occurs.

The Gross 2 reference describes a protective displaceable cover 303 which can be coated with an adhesive and applied to a skin surface, wherein pushing down on the top of the device moves the cover 303 upward to a retracted position, and pulling upward on the top of the device allows the secured adhesive layer to move the cover 303 downward to an extended position. A resistance to movement is provided by the rounded projections at ends thereof and which are displaced in notches 305 and 306 in the top of the device (see Figs. 15 and 16, and col. 13, lines 25-35).

In the Advisory Action of February 28, 2011, the Examiner asserts that “the claims do not recite any limitations as to what constitutes device activation”, and that the pushing and pulling of the device in Gross 2 results in the safety member release as recited by the Applicants. In Gross 2, it appears that the pressing downward of the device pushes the guard 303 and detents up and into recesses 306 in the top of the device (see Figs. 14 and 15), and the removal of the device from the skin surface pulls the guard 303 and detents down and into recesses 305 in the top of the device (see Figs. 13 and 16, and Abstract).

However, there is no disclosure in Gross 2 that the projections are released from the notches 305 or 306 by movement of a device activation button. That is, the notches and detents of Gross 2 are simply provided to hold a retracted or extended position of the cover 303 against minimal resistance. In contrast, the Applicants recite a system and method wherein movement of the device activation button releases the safety member, and adhesion with the skin surface rotates the released safety member. The Applicants recite that the safety member is released by movement of the device activation button such that, when the device is removed from the skin surface, adhesion of the safety member to the skin surface is permitted to rotate the safety member.

However, to expedite prosecution, the Applicants have amended independent claim 3 to recite that the device activation comprises at least activation button movement and in doing so, *contact* between a *safety member surface* and the *activation button* is released, such that the safety member is no longer prevented from rotational movement by such

contact with the activation button. Specifically, the Applicants have amended the claims to recite a safety member comprising at least one surface configured to contact and be held in place by the device activation button to prevent rotational movement, and wherein the safety member is released by movement of the device activation button from contact with the safety member.

In regard to Gross 2, even where the top surface of the device is considered allegedly a device activation button and the cover 303 a safety member, the two elements remain in contact in each position. That is, the cover 303 remains in contact with the alleged device activation button of Gross 2 and the device activation button never moves from contact with the safety member as recited by the Applicants. In fact, the cover is held in both extended and retracted positions by such an alleged device activation button of Gross 2 and arguably, held (with less force) in each position there between by such an alleged device activation button of Gross 2.

In regard to Gross 1, no surface of a safety member is shown that is configured to contact and be held in place by a device activation button to prevent rotational movement of the safety member. Where the base 22 is considered an alleged safety member and the top housing 11 considered an alleged device activation button, the base 22 is never secured from movement by any feature of the housing 11. Movement of either element is simply restricted by the safety tab 27 which once removed, allows the device to be pressed downward into service. Pulling away of the housing 11 allows the adhesive covered base 22 to remain, and a re-use prevention mechanism 44-46 can be provided to prevent re-use.

Also in regard to Gross 1, a snap mechanism is briefly mentioned (see col. 8, lines 26-34, and col. 9, lines 4-14), but is not described or shown in detail, and appears to describe a system much like that of Gross 2, in which any snap-action type securing between the top housing and base is maintained at each position, but having certain positions with greater resistance than remaining positions.

The Applicants have also added new dependent claims 7-17 to recite exemplary embodiments of the safety member and features thereof, including features of the exemplary surface configured to contact and be held in place by the device activation button to prevent

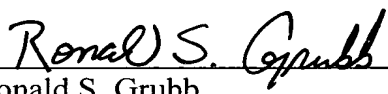
movement of the safety member. Such features can include detents, detent arms, and various openings and shoulders of the safety member and the activation button to hold the safety member when the activation button is in one position, and free the safety member when the activation button is moved (see for example, Figs. 39 and 125).

Accordingly, for at least these reasons, the Applicants assert that the Lavi, Hart, Gross 1 and Gross 2 references, separately or in combination, do not disclose or reasonably suggest each element as recited in independent claims 1, 2 and 3, and respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a). Dependent claims 4-17 which are dependent from claims 1, 2 and 3, are allowable for at least these reasons.

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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